

## REMARKS

By an Office Action dated May 13, 2004 in the file of this application, the claims of this application were first rejected in the Office Action based on a rejection under 35 U.S.C. §112, on the grounds that the specification while enabling for a specific extract does not provide enablement for the claimed product beyond that which is exemplified in the specification. The applicants respectfully traverse this requirement.

The applicants agree that it is a requirement that the application contain a written description of the invention sufficient for those of ordinary skill in the art. It is submitted by the applicants here that one of ordinary skill in the art of *in vitro* protein expression system knows what is meant by “S-30 extract.” As evidence of that the applicants would like to refer again to the numerous scientific papers and products offered for sale referred to in Appellant’s Brief, already in the file of this patent application. The evidence that those of ordinary skill in the art understand this term is that they use it with regularity to describe and identify a specific biological product, a protein expression extract made from prokaryotic cells. It is a well recognized and understood product sold in commerce and identified in technical literature by this name. The term has meaning to those of ordinary skill in the art.

As it may be of interest, it is worth noting that other patent examiners have not had great difficulty in understanding this term as used in a patent claim. During the pendency of this patent application, U.S. Patent No. 6,532,522 issued. Claim 11 of that patent specifically mentions an S-30 extract from *E. coli* using language similar to that used in the present application.

Nevertheless, to test the limits of what the Examiner finds to be patentable, new Claim 31 has been presented. In Claim 31 the S-30 extract is defined by the process of preparing it as suggested by the Examiner. The process of preparing it is described based on the method steps described in the specification in paragraphs [0042] to [0045] of this patent application.

In the thought that perhaps it is the word “extract,” to which the Examiner objects, Claim 32 has also been presented which omits that specific word, and instead describes the material as a transcriptional and translational component. The wording for transcriptional and translational component is found in paragraph [0004] on page 1 of the specification.

Claim 33 is intended to do both modifications in a single claim, that is avoid the use of the word “extract” and also define the transcriptional and translational components by the method of their preparation. This is being done in an effort to find some verbal formulation to which the Examiner will not object.

With regard to the next rejection, under second paragraph of 35 U.S.C. §112, the Examiner still rejects the claims as indefinite for reasons stated before. The applicants continue to believe and assert that the Examiner is absolutely incorrect and has filed an Appeal Brief on that section. The arguments presented in the Appeal Brief are re-incorporated herein in their entirety by reference.

The Examiner is attempting to extract quotations from the Appellant's Brief and asserts that there is some inconsistency in between them. The inconsistencies are only in the Examiner's interpretation and not in the true meaning of the words.

The applicants have supplied to the Examiner all enabling data required to practice this invention. The applicants have cited papers and have described in the specification of this application the exact methodology by which the applicants' improved extract is made. The Examiner has argued that the applicants have refused to provide some sort of necessary information. This is not true. The applicants have told as recited in this application all of the details on how their product is made.

In support of the argument that the applicants are hiding something, the Examiner cites the website of the applicants with regard to its EcoPro product. The EcoPro system is, in fact, the product described in this patent application. On the website, the narrative does say that the extracts are prepared with a "proprietary fractionation process." It is hoped that the process will be proprietary, but what that means is that there is a patent application pending attempting to cover that process. That patent application is this precise patent application. The method of preparation of that fractionation is specifically described in this patent application in the second half of paragraph [0030], in paragraph [0031] and in paragraph [0047] of the specification. The results described from the use of the fractionated reaction mixture is described as well in the specification. There is nothing hidden. All of the details on the method of making and using the claimed product is contained within this specification. The applicants have not omitted anything.

On page 9 of the Office Action the Examiner imposes a new rejection under best mode under 35. U.S.C. §112, first paragraph. This rejection is improper since the applicants have disclosed everything they knew at the time of filing this patent application about how to make the product described by this patent application. The only thing "proprietary" about the process was that Novagen was attempting to patent that process, through this patent application. All of the details on how the product was made are described in this patent specification. Since nothing is hidden, there can be no best mode rejection.

Lastly, the Examiner imposed a rejection under 102 and 103 on the grounds that Chen et al. or Zubay or Lesley et al. anticipate the claims of this patent application. These

rejections are all wrong. Note that in the specification of the present invention the S-30 extract is combined with a reaction mixture prior to freezing. This is explicitly recited in, for example, Claim 7 which specifically recites that the reaction mixture includes the prokaryotic S-30 extract is combined with the supplemental mix of nucleotide triphosphates and an energy source. Only then is the combined reaction mixture frozen and fractionated. As carefully set forth in the patent application, normally an S-30 extract is not combined with the supplemental mix until the time that transcription and translation is to be performed. Nothing in the cited papers shows the idea of mixing the S-30 extract with the supplemental mix and then fractionating the combined mixture.

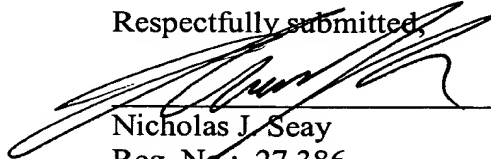
In the Chen et al. paper an S-30 extract is prepared and described as such, using those exact words, on pages 675 and 676. The S-30 extract is thawed and then used immediately in a transcription translation reaction as described specifically on page 676 of the paper. No fractionation of the S-30 extract is performed in this paper, as is required by the claims of this application.

The Zubay paper does recite the creation of S-30 extracts. The preparation of the extract is described on pages 275 to 276. Again it is recited that the extract is frozen and stored for use, but is used immediately after thawing without fractionation. See for example the last two sentences on the end of the paragraph bridging pages 275 and 276. No fractionation or freezing is performed after the S-30 extract is combined with a reaction mix. The same is true of the reference to Lesley et al. Note that the specification and claims of this application specifically requires that the extract be mixed with the supplemental mixture and then frozen, thawed and fractionated. This is not shown in any of the references cited by the Examiner.

Thus the rejections on prior art are not supported by a fair reading of those papers and should be withdrawn.

Wherefore it is asserted that the rejections applied against the claims of this application are incorrect and a reconsideration of the merits of this patent application is respectfully requested based on this submission. This submission is accompanied by a petition for extension of time so that it will be considered as timely filed.

Respectfully submitted,



Nicholas J. Seay  
Reg. No.: 27,386  
Attorney for Applicants  
QUARLES & BRADY LLP  
P.O. Box 2113  
Madison, WI 53701

TEL 608/251-5000  
FAX 608/251-9166